REMARKS

The following remarks are being submitted as a full and complete response to the Office Action dated April 11, 2006, in view of which the Examiner is respectfully requested to give due reconsideration to all outstanding rejections and/or objections, that they be withdrawn, and to indicate the allowability of the claims, and to pass this case to issue.

Status of the Claims

Claims 1-3 are pending in the application and have all been amended. Claims 4-6 stand withdrawn pursuant to Examiner's imposed restriction requirement. No new matter has been added.

Rejection under 35 U.S.C. §112, 2nd paragraph

Claims 1-3 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

Accordingly, claims 1-3 have been amended to obviate this ground for rejection and it is respectfully requested that it be withdrawn. In particular, claim 1 has been amended to more precisely point out that the invention relates to evaluation of efficacy of interferon β treatment against multiple sclerosis and that evaluation of efficacy involves checking the levels of gene expression in a subject patient against established correlations of clinical findings of sample patients and expression levels of those interferon β induced genes. Regarding algorithm for correlating clinical findings with gene expression levels, such algorithm is expressly not a limitation of claim 1. One of ordinary skill in the art can use any statistical algorithm, including those taught in the specification, but by no means is it necessary to so narrow the scope of claim 1 by limiting it to the use of a particular algorithm.

In effect, the current invention relates to accumulating empirical data on gene expression levels pursuant to Interferon β treatment and subsequently using that as a basis to evaluate the efficacy of Interferon β treatment in patients with multiple sclerosis by tracking the expression of those genes. In other words, the efficacy of Interferon β treatment against multiple sclerosis is evaluated by statistically analyzing variation in the gene expression levels of a patient's peripheral blood leukocytes using a specific gene cluster disclosed in the instant invention as a marker. (p16, lines 15-20).

Claim 1 as currently written, very distinctly therefore, reflects what Applicants regard as their invention and it is again respectfully requested that this ground for rejection be withdrawn.

Rejections under 35 U.S.C. §103

Claims 1 stands rejected under 35 U.S.C. §103(a) as allegedly obvious over Sharp US 2003/0104393, in view of Veer, Genomics, 54:267-277 (1998), and further in view of Satoh, Neurology, 57:681-685 (2001).

The Examiner asserts that Sharp discloses a method of assessing an effect in an organism caused by different factors based on gene expression profile. The Examiner acknowledges that Sharp did not specifically disclose interferon induced and interferon regulated protein genes, nor did Sharp specifically disclose an interferon β treatment. Applicants add that Sharp is far more deficient in respect of the instant invention than the Examiner has acknowledged and the deficiencies in Sharp are not cured by the adjunct references under 35 U.S.C § 103(a).

Sharp did not disclose the use of interferon induced genes as a means of monitoring the efficacy of Interferon β treatment of multiple sclerosis. Moreover, Shard did not teach nor suggest such analysis occuring by way of gene expression of peripheral blood leukocytes for every disease. Very few diseases can be analyzed by the gene expression of peripheral blood leukocytes. It is not possible from Sharp to estimate the efficacy of interferon ß against multiple sclerosis. The mechanism of multiple sclerosis has not even been known. In Sharp, there is no disclosure that the genes in the instant invention are a maker for analysis of the efficacy of the interferon ß treatment against multiple sclerosis using peripheral blood leukocytes of the patient. For that at least, the combination asserted by the Examiner does not teach nor suggest, explicitly or inherently the instant invention as claimed and it is respectfully requested that this ground for rejection be withdrawn.

Veer discloses IFIT4 expression which is regulated by interferon ß (p 274). However, there is no teaching or suggestion in Veer that at least one interferon induced protein gene, regulatory factor gene, or chemokine gene is a maker for analysis of the efficacy of the interferon ß treatment against multiple sclerosis using peripheral blood leukocytes of the patient.

Nor is the deficiency in Sharp and Veer cured by Satoh. Satoh discloses expression of IRF7 by interferon ß (p 683). However, the sample is not peripheral blood leukocytes but the

astrocytes isolated from the brain of a human fetus at 19 weeks (p 682) that is not in multiple sclerosis. There is no teaching or suggestion in Satoh that the genes in the instant invention are a maker for analysis of the efficacy of the interferon ß treatment against multiple sclerosis using peripheral blood leukocytes of the patient.

Without addressing the merits of the combinability of Satoh, Sharp and Veer, Applicants contend that even if the combination is proper, the combined art does not disclose what has been claimed in the instant invention. For that at least, this ground for rejection is obviated and should be withdrawn.

Claim 2 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sharp in view of Veer, in view of Satoh, as applied to claim 1 above and further in view of Nomiyama, J. Interferon and Cytokine Res., 19(3): 227-234(1999). According to the Examiner, Nomiyama discloses a plurality of members of chemokine family comprising SCYA1, SCYA2, and SCYA9. However, none of the cited art, either separately or in combination teaches or suggests that the genes of the instant invention are a marker for analysis of the efficacy of interferon β treatment against multiple sclerosis using peripheral blood leukocytes of the patient. For that at least, it is respectfully requested that this ground for rejection be withdrawn.

Request for Search and Examination of Other Species

This invention was subjected to species election in order to aid the Examiner in conducting a search and examination of the claimed subject matter. Applicants respectfully request that since the elected species is believed by the Applicants to be allowable over the prior art, that the Examiner expand the search to cover other species up to and including the full scope of the generic claims included in the elected group.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason

that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

Stanley P. Fisher
Registration Number 24,344

Juan Carlos A. Marquez
Registration Number 34,072

Toni-Junell Herbert
Registration Number 34,348

REED SMITH LLP
3110 Fairview Park Drive, Suite 1400
Falls Church, Virginia 22042
(703) 641-4200
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SPF/JCM/TH/CEA